

**International Implications of the Proposed**  
***WMD Prevention and Preparedness Act of 2010***

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Good afternoon, Chairwoman Clarke, Congressman Lungren, Congressman Pascrell, Congressman King, and distinguished members of the Subcommittee. Thank you very much for giving me the opportunity to offer comments on H.R. 5498, the proposed *WMD Prevention and Preparedness Act of 2010*.

National and international responses to biological threats have evolved dramatically in the past decade. Following the anthrax assaults of 2001, Congress created legislation to promote biosecurity in the nation's research and clinical laboratories, and to strengthen national capacities to respond effectively to public health crises. Measures broadened the regulations that govern access to "Select Agents," pathogens and toxins deemed a serious threat to public health and security if released. The Department of Health and Human Services (HHS) administers oversight of laboratories that possess, use, or transfer human pathogens on the Select Agent list, and the U.S. Department of Agriculture (USDA) serves a parallel role for laboratories that study plant and animal pathogens.

Since the implementation of the Select Agent regulations, these agencies and the biomedical research community have sought a delicate balance: how to apply the regulations in a way that meaningfully enhances biosecurity, without hindering the ability of laboratories to conduct legitimate clinical testing and research. The latter is all the more significant in that the research under scrutiny ultimately builds the public health toolkit of diagnostics, vaccines, and treatments against infectious diseases, including those that might be used as biological weapons.

Although primarily aimed at U.S. clinical and biomedical research laboratories, the Select Agent regulations have affected international collaborations. Many pathogens on the Select Agent list cause natural disease outbreaks in other regions. U.S. and international researchers based in countries where such pathogens are prevalent benefit mutually from partnerships that include sharing of knowledge, skills, and specimens. An unknown number of U.S. researchers severed international collaborations following implementation of the Select Agent regulations, impairing progress and reducing the influence of U.S. scientists within international communities of practice. The costs and benefits of security measures that might further imperil such

collaborations, or obstruct cooperation during an international public health emergency, must be weighed carefully.

The legislation introduced by Congressmen Pascrell and King would address many of the lessons learned since 2001, including recommendations by the bipartisan Commission for the Prevention of Weapons of Mass Destruction Proliferation and Terrorism. The proposed act recognizes gaps in our abilities to respond to events that could jeopardize public health and national security. Public and private sector stakeholders in the life sciences still struggle to balance cultures of responsibility and fear in addressing potential vulnerabilities. The proposed legislation confronts another balancing act: how to improve coordination and integration of the myriad programs that have evolved to tackle biological threats without creating new layers of oversight that might rob existing efforts of their momentum.

## **Prevention and deterrence**

A common criticism of the Select Agent regulations has been the application of a “one size fits all” security strategy to all of the listed pathogens, even though the public health, scientific, and security communities recognize a gradient of risks. The proposed legislation would require enhanced biosecurity measures for laboratories that possess, use, and transfer “Tier 1 Material Threat Agents.” A new emphasis on risk-based security measures could allow stakeholders to set priorities more effectively, focusing their resources on the subset of laboratories where risks are most evident. The proposed legislation implies that the “Tier 1” agents would include fewer pathogens than the current Select Agent list. However, the criteria that would be used to distinguish “Tier 1” agents from Select Agents are not described in detail, aside from the inclusion of Bioterrorism Risk Assessments in considerations. The legislation would designate the Department of Homeland Security (DHS) to lead an interagency rule-making process to develop the enhanced biosecurity measures, including laboratory practices. Notwithstanding the laudable attempt to mandate inclusion of the broader stakeholder community, this could further complicate existing dual HHS and USDA oversight. The proposed legislation does not describe how these new “Tier 1” practices would be managed in relationship to the existing Select Agent

regulations at the national or institutional level, or whether standards would be relaxed for institutions possessing Select Agents newly categorized as lower-risk.

The legislation would authorize awards to offset increased security costs at “Tier 1” laboratories, based on risk. While a welcome response, it is unclear how risk would be evaluated, or whether academic and non-profit organizations that receive such funds could use them to help overseas partners comply with any new controls on pathogen acquisition, storage, transfer and use. In the absence of such assurance, and pending further detail on the Tier 1 Material Threat Agent determination process, it is difficult to say whether these measures might further isolate U.S. researchers investigating Tier 1 pathogens from their international counterparts.

The proposed network to coordinate customs and export regulation enforcement under DHS emphasizes enhanced operational relationships, rather than new authorities. However, in this context – particularly given the reference to “dual-use” technologies, a term that includes a broader swath of activities and materials in the life sciences than commonly applied to commodities with military applications – this emphasis could reinvigorate apprehensions at home and abroad about the open sharing of information resulting from unclassified research.

## **Detection**

Biosurveillance systems face new demands to provide warning of extraordinary events. In response, stakeholders have expanded their capabilities to detect and characterize public health events that could become national, or transnational, threats.

The SARS outbreak of 2003 demonstrated the costs of one nation’s failure to report an emerging infectious disease outbreak – whether due to lack of capacity or lack of will – in an era of rapid international travel. The human, political, and economic tolls helped catalyze adoption of the revised International Health Regulations by the World Health Organization’s member states in 2005 [IHR (2005)]. The IHR (2005) require the 194 state parties to strengthen their capacities for public health surveillance and response, and to report any deliberate, natural, or accidental events that might affect health across national borders. The regulations also vested WHO with

new authorities to collect and share information on such events. Unlike other global health initiatives that aim to strengthen capacities for disease detection, assessment, reporting, and response, the IHR (2005) are legally binding. They enjoy relatively widespread international support, and complement the objectives of both the Biological and Toxin Weapons Convention and the recently released U.S. National Strategy for Countering Biological Threats.

The U.S. has also stepped up its attempts to integrate its fragmented disease surveillance networks. Public Law 110-53 charged DHS with overseeing the development and operation of the National Biosurveillance Integration System (NBIS), including the National Biosurveillance Integration Center, an effort slowed at its outset by logistical and management challenges. Homeland Security Presidential Directive-21 delegated the task of establishing a national biosurveillance system for human health to HHS. With input from the interagency Federal Biosurveillance Work Group and other stakeholder committees, the U.S. Centers for Disease Control and Prevention (CDC) developed the National Biosurveillance Strategy for Human Health delivered in February 2010. This strategy encompasses a framework for improving the timely, multi-directional flow of health-related information among local, state, and Federal stakeholders and with global partners. As implied by the proposed legislation, DHS could play a stronger leadership role in leveraging operationally useful health-related data and information for decision makers across all levels of government. This should build upon the existing national biosurveillance strategy for human health, laboratory networks and biomonitoring programs.

## **Attribution**

The legislation would require public and private entities that have received Federal funding to provide samples of biological agents and toxins for a proposed national bioforensics repository collection. Others here today will doubtless comment more comprehensively on the tools for attributing biological attacks to likely perpetrators. I would like to highlight additional sensitivities in including organisms derived from international partnerships or collections.

Many emerging economies already perceive the motives of the U.S. and the international community in collecting specimens for legitimate public health interventions as less than

transparent. The proposed repository would explicitly include international collections and implicitly encompass agents originally derived by U.S. researchers from international partnerships. Including agents that trace their origins to international collaborations, perhaps even to third-party countries, could inflame tensions that already endanger specimen sharing under the IHR (2005) and other global disease surveillance networks. The potential effects on U.S. engagement in global health should be factored into the examination of access and participation issues laid out in the proposed legislation.

### **International Collaboration and Engagement to Enhance Biodefense and Biosecurity**

As recognized by the legislation's authors and articulated in the recommendations of the Commission for the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, situational awareness for biological risks depends on capabilities far beyond U.S. borders. In an era of accelerated globalization, no nation, no matter how technologically advanced, can build tall enough walls to keep out infectious diseases and other public health risks.

This legislation acknowledges the critical need for the U.S. to support capacity-building in other nations to strengthen mechanisms for detecting and reporting unusual events that could presage a deliberate, accidental, or natural infectious disease outbreak. However, the language does not yet encompass the breadth of Federal players, international platforms, and potential risks that are already part of the U.S. global health security engagement strategy. The designation of the Secretary of State as the lead actor in U.S. biosecurity engagement abroad recognizes ongoing efforts by organizations such as the State Department's Bioengagement Program. However, in addition to the agencies directly identified in the proposed legislation, other Federal agencies and divisions of agencies, including the Department of Defense, CDC, the U.S. Agency for International Development, and elements of the U.S. national laboratories, have significant presence in public health capacity-building efforts abroad. An interagency process is underway to develop an operational framework for implementing the capacity-building objectives in the U.S. National Strategy for Countering Biological Threats. The proposed legislation's focus on building capacity to report "validated data on biological attacks" to United Nations organizations does not parallel the terminology of the IHR (2005), which refer to detecting and reporting

“public health emergencies of international concern.” This might inadvertently jeopardize U.S. and international efforts to support implementation of the IHR (2005) as a common global platform for disease detection and response, including deliberate biological threats.

International collaboration is an important tool in building shared norms, and U.S.-supported capacity-building projects in the life sciences increasingly build long-term partnerships that promote trust, openness, and converging research priorities. The proposed legislation acknowledges the benefits of such engagement, directing the Secretary of State to support partner nations’ efforts to enhance biosafety and biosecurity, taking their own priorities in comprehensive biorisk management into account. Language in the proposed provisions that would generally promote data-sharing among federally supported programs abroad for biosecurity purposes might reinforce negative perceptions of U.S transparency and motives.

### **Interagency Task Force on Best Practices for Global Biopreparedness**

The last decade has witnessed a rapid growth of public health preparedness capabilities at home and abroad. Domestically, the U.S. has supported efforts to share lessons learned during events and exercises among first responders in an effort to strengthen all-hazards preparedness at the local, state, and Federal levels. Clearly, other nations face the same need to build response capabilities across levels of government, and many do so without the resources available in the U.S. and other high-income nations. Concerns about exposing homeland security vulnerabilities have limited open information-sharing about lessons learned in disaster response with first responders outside of the U.S. The U.S. is certainly not the only nation to hold the results of simulations and self-assessments in public health preparedness close.

Several recently developed mechanisms answer the need to help nations identify and implement best practices to prevent, detect, or respond to biological and other catastrophic threats. The IHR (2005), under the aegis of WHO, provide an international forum for assessing and strengthening the global architecture for public health preparedness. United Nations Security Council Resolution 1540, through the work of the 1540 Committee, provides an information clearinghouse and means for capacity building to prevent proliferation of weapons of mass

destruction, including bioweapons. The U.S. plays a significant role in assisting partner nations with their obligations under these frameworks.

By creating a U.S. interagency task force on global biopreparedness architecture, the legislation would spark a discussion of new developments and persistent gaps among a broadly inclusive group of stakeholders. The result, if viewed as a map of needs, vulnerabilities, and potential partnerships, could help the U.S. develop a more targeted strategy for building global pathogen surveillance and response capacities. It is unclear whether this task force would be charged with considering only the architecture for a deliberate biological event, or for natural outbreaks and accidental releases as well. It is possible that this task force could overlap substantially with activities currently being developed under the National Strategy for Countering Biological Threats. It is also possible that recommendations for a global preparedness architecture developed outside of any international forum in which the U.S. is a key stakeholder may not be adopted with wholesale enthusiasm by the international community.

## **Conclusions**

Overall, the proposed legislation would address many weaknesses in sharing and integration of health-related information, particularly at the state and local level. Stronger integration of public health expertise into the security and intelligence communities could help make data on disease threats more relevant for strategic and tactical planning across all levels of government. Many of the provisions in H.R. 5498 resolve earlier concerns voiced in response to earlier legislation introduced in the Senate, and carefully recognize the very dynamic nature of the field. In fact, that will be one of the hardest problems that this subcommittee will face as it considers this legislation: the rapid changes in U.S. and global biosurveillance programs, strategies, and ground truths that change the landscape for biopreparedness in days rather than weeks or months.